

Attorney Docket No.: 930008-2210 (BOE0006US.NP)
Inventors: Runge and Lembcke
Serial No.: 10/593,657
Filing Date: April 16, 2007
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This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (original): Pharmaceutical formulation comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance.

Claim 2 (original): Pharmaceutical formulation according to claim 1 comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance, wherein the formulation is in the form of a tablet with a content of at least one flow regulator.

Claim 3 (original): Pharmaceutical formulation according to claim 1 comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance, wherein the formulation is in the form of a filling for capsules.

Claim 4 (original): Pharmaceutical formulation according to claim 1 comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance, wherein the formulation is in the form of a dragée, effervescent tablet, suppository or granulate.

Claim 5 (original): Formulation according to at least one of the preceding claims comprising flutamide of a particle size such

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as is formed in the synthesis process with subsequent purification step(s).

Claim 6 (original): Formulation according to claim 5 comprising flutamide of a particle size such as is formed in the synthesis process with recrystallisation as a subsequent purification step.

Claim 7 (original): Formulation according to at least one of the preceding claims comprising flutamide of a mean particle size greater than the mean particle size of flutamide that, with an initial particle size of from 5 to 240 μm , has been subjected to a milling operation.

Claim 8 (original): Formulation according to at least one of claims 1 to 7 comprising flutamide in which the size of 50% of the flutamide particles (X50 value) is greater than 20 μm .

Claim 9 (original): Formulation according to claim 8 comprising flutamide in which the size of 50% of the flutamide particles (X50 value) is greater than 26 μm .

Claim 10 (original): Formulation according to at least one of claims 1 to 7 comprising flutamide in which the size of 90% of the flutamide particles (X90 value) is greater than 60 μm .

Claim 11 (original): Formulation according to claim 10 comprising flutamide in which the size of 90% of the flutamide particles (X90 value) is greater than 130 μm .

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Claim 12 (original): Formulation according to at least one of the preceding claims comprising flutamide of a specific surface area of less than $2.50 \text{ m}^2/\text{cm}^3$.

Claim 13 (original): Formulation according to claim 12 comprising flutamide of a specific surface area of less than $1.50 \text{ m}^2/\text{cm}^3$.

Claim 14 (original): Formulation according to claim 13 comprising flutamide of a specific surface area of less than $0.35 \text{ m}^2/\text{cm}^3$.

Claim 15 (original): Formulation according to at least one of the preceding claims comprising flutamide in the form of the free acid amide and/or of a pharmaceutically acceptable solvate.

Claim 16 (original): Formulation according to at least one of the preceding claims comprising at least one surface-active substance selected from the group formed by

- anionic compounds,
- cationic compounds and
- non-ionic surfactants.

Claim 17 (original): Formulation according to claim 16 comprising sodium dodecylsulphate as surface-active substance.

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Claim 18 (original): Formulation according to at least one of the preceding claims with a ratio by weight of flutamide: surface-active substance(s) of from 5 : 1 to 30 : 1.

Claim 19 (original): Formulation according to claim 18 with a ratio by weight of flutamide : surface-active substance(s) of from 5 : 1 to 20 : 1.

Claim 20 (original): Formulation according to claim 19 with a ratio by weight of flutamide : surface-active substance(s) of from 10 : 1 to 15 : 1.

Claim 21 (original): Formulation according to at least one of the preceding claims in the form of an unshaped mixture or in the form of an article that has been subjected to shaping.

Claim 22 (original): Formulation according to claim 21 with a content of from 50 to 2000 mg of flutamide.

Claim 23 (original): Formulation according to claim 22 with a content of from 50 to 500 mg of flutamide.

Claim 24 (original): Formulation according to claim 23 with a content of from 100 to 200 mg of flutamide.

Claim 25 (original): Formulation according to at least one of the preceding claims with a content of at least one excipient from the group formed by inorganic fillers, organic fillers,

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binders, glidants, lubricants, flow regulators and/or disintegrants.

Claim 26 (canceled).

Claim 27 (original): Process for the preparation of a pharmaceutical formulation according to at least one of claims 1 and 5 to 26 comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance, in which the flutamide is subjected to an intensive mixing process with the at least one surface-active substance.

Claim 28 (original): Process for the preparation of a pharmaceutical formulation according to claim 2, 3 or 4 comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface active substance, in which the flutamide is subjected to an intensive mixing process with the at least one surface-active substance, and the mixture obtained is further processed to form a formulation according claim 2, 3 or 4.

Claim 29 (original): Process according to claim 27 or 28 in which mixing is carried out at a temperature of from 0 to 40°C.

Claim 30 (original): Process according to claim 29 in which mixing is carried out at room temperature.

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Claim 31 (original): Process according to at least one of claims 27 to 30 in which one or more excipients are admixed using a forced-action mixer or using a free-fall mixer.

Claim 32 (canceled).

Claim 33 (original): Process according to at least one of claims 27 and 29 to 32 in which the mixture obtained is further processed to form tablets, capsules, dragées, effervescent tablets, suppositories or a granulate.

Claim 34 (original): Process according to claim 28 and/or according to claim 33 in which the mixture obtained is subject to direct tableting.

Claim 35 (original): Process according to claim 28 and/or according to claim 33 in which the granulate is further processed to form tablets.

Claim 36 (original): Pharmaceutical formulation comprising crystalline and/or amorphous unmilled flutamide mixed with at least one surface-active substance, producible in accordance with a process according to at least one of claims 27 to 35.